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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,831	08/18/2000	C. Alexander Turner JR.	LEX-0035-USA	6428

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/641,831	Applicant(s) TURNER ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to isolated nucleic acids comprising at least 24 contiguous nucleotides of a NHP sequence of SEQ ID NO: 1, 3, or 5, nucleic acids which hybridize under stringent conditions to SEQ ID NO: 1, 3 or 5, and nucleic acids encoding the amino acid sequence of SEQ ID NO: 2, 4 or 6. The specification refers to these nucleic acids as encoding NHPs (novel human proteins). The claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well-established utility. The specification fails to provide objective evidence of any activity for the encoded polypeptides. Rather, the specification indicates that homology studies show that the putative proteins have identity with "a variety of putative secreted proteins, a tyrosine phosphatase, several human LIM proteins, as well as several cancer (colon, renal, and lung) associated antigens" (page 12). It is further stated that the NHPs "share structural motifs typical of the human APXL protein- a protein that is similar to a Xenopus amiloride sensitive sodium channel" (page 2). While the specification

states that the sequences of the polynucleotides have homology to other known proteins, the specification does not set forth a specific level of sequence identity shared, over the complete sequence, between the claimed polynucleotides and known polynucleotides encoding transporter proteins. Identity of a polynucleotide sequence to other known polynucleotides does not by itself establish that a polynucleotide will encode for a product having the same activity as the known polynucleotides because a change at even a single amino acid position may affect a proteins function and a change at a single nucleotide position may affect the ability of a polynucleotide to encode for a polypeptide. Furthermore, no information is provided regarding the conservation of any particular domains which are required for transporter function or which are characteristic of specific types of transporter proteins. Accordingly, there is no evidence of record to suggest that the claimed polynucleotides do in fact encode for polypeptides a particular activity. In addition, the specification does not distinguish between which polynucleotides have identity to APXL, which have identity to "secreted proteins", which have identity to a tyrosine phosphatase, which have identity to a LIM protein, and which have identity to a cancer antigen. Moreover, these types of proteins fall into very general classes of proteins and are not considered to constitute a specific activity for utility purposes. The specification (for example, 12) suggests that the claimed polynucleotides could be used for therapeutic purposes or for diagnosis of disease. However, no specific diseases have been identified which are correlated with expression of the claimed polynucleotides. Clearly, further research would be required to identify a disease for which the encoded protein is involved and for which treatment with the encoded proteins

would be effective or for which detection of expression of SEQ ID NO: 1, 3 or 5 would be informative. As stated in Brunner v. Manson, 383 U.S. 519 535-536, 148 USPO 689, 696 (1966) " a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". The specification (see, for example, pages 30, 35 and 38) further asserts that the polynucleotides of SEQ ID NO: 1, 3 and 5 and the proteins of SEQ ID NO: 2, 4 and 6 can be used in drug screening methods. However, because the specification has not established that the proteins of SEQ ID NO: 2, 4 and 6 have a functional activity, the general concept of using any compound for the purposes of screening for agents which bind this compound is not considered to be a specific utility. While nucleic acids comprising SEQ ID NO: 1, 3 and 5 could be expressed to obtain protein for use in research aimed at determining or characterizing the polypeptides function, such use is general, rather than specific and substantial. Support for an asserted utility that is specific and substantial would require, for example, a showing of a particular function for an encoded polypeptide. Merely identifying and studying the properties of a polypeptide or the diseases in which a polypeptide may be involved does not constitute a "real world" context of use. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

3. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, or credible asserted utility

or well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to isolated nucleic acids comprising at least 24 contiguous nucleotides of a NHP sequence of SEQ ID NO: 1, 3, or 5 and nucleic acids which hybridize under stringent conditions to SEQ ID NO: 1, 3 or 5. The specification teaches nucleic acids consisting of SEQ ID NO: 1, 3 and 5 and nucleic acids encoding the amino acid sequence of SEQ ID NO: 2, 4 and 6. The specification refers to these nucleic acids as encoding NHPs (novel human proteins). The specification fails to demonstrate that the putative proteins have any particular activity. Rather, the specification indicates that homology studies show that the putative proteins have identity with "a variety of putative secreted proteins, a tyrosine phosphatase, several human LIM proteins, as well as several cancer (colon, renal, and lung) associated antigens" (page 12). The specification further states that NHPs are intended to include fragments, mutated, truncated and deleted forms and encompasses molecules which are "functionally equivalent " as judged by, for example, their ability to bind a receptor or ligand of a NHP, the ability to effect an identical or complementary signal transduction pathway or a change in cellular metabolism (see pages 12-13 of the specification). The claims as broadly written also

include nucleic acids in which sequences are present flanking 24 mer fragments of SEQ ID NO: 1, 3 or 5. The broadest reasonable interpretation of the claims indicates that the claims are inclusive of NHP genes and NHP genomic sequences. However, the specification does not teach any full length NHP genes or any NHP genomic sequences. The claims are further inclusive of cDNAs and genomic DNAs comprising any 24 mer fragment of SEQ ID NO: 1, 3 or 5 or any fragment of any length which hybridize under stringent conditions to SEQ ID NO: 1, 3 or 5. The phrase "stringent conditions" is not adequately defined in the specification, and this term has been interpreted as including low stringency conditions. Thereby, the claims include a huge genus of nucleic acids comprising fragments which have 20%, 30%, etc identity with SEQ ID NO: 1, 3 or 5. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In

the instant case, only 3 members of the broadly claimed genus have been defined by their structure, i.e. SEQ ID NO: 1, 3 and 5. No genomic sequences flanking SEQ ID NO: 1, 3 or 5 have been defined. No additional genes, encoding proteins having any function or a function equivalent to SEQ ID NO: 2, 4 or 6, have been defined which contain 24 mer fragments of SEQ ID NO: 1,3 or 5 or which contain fragments which hybridize under stringent conditions to SEQ ID NO: 1, 3 or 5. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, chromosomal map position, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of the polynucleotides. The broad definition given for the functional activity of NHPs provided in the specification is not sufficient to clearly define the functional activity of the encoded proteins. In addition, the claims do not actually set forth any functional property for the nucleic acids. Furthermore, defining a nucleic acid in terms of only 24 residues or in terms of an unspecified number of residues which hybridize under stringent (i.e. any) conditions to SEQ ID NO: 1, 3 or 5 does not provide an adequate structural description of the nucleic acids because the flanking nucleotides are completely undefined. In addition, defining a nucleic acid in terms of the fact that it hybridizes to SEQ ID NO: 1, 3 or 5 is such a broad definition that it is not considered to adequately further characterize the structure of the nucleic acid. While at the time of filing, applicants were in possession of nucleic acids consisting of SEQ ID NO: 1, 3 and 5 and nucleic acids encoding SEQ ID NO: 2, 4 and 6, the specification provides no information regarding

genomic sequences surrounding the sequences of SEQ ID NO: 1, 3 and 5 and does not identify any nucleic acids comprising 24 mer fragments of SEQ ID NO: 1, 3 or 5 or nucleic acids which comprise fragments which hybridize under stringent conditions to SEQ ID NO: 1, 3 or 5. Accordingly, a representative number of species encompassed by the genus of claimed nucleic acids are not disclosed in the specification . For these reasons, the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

5. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are indefinite over the recitation of "NHP" because it is unclear as to what constitutes a novel human protein. Since all issued products are considered to be novel, the use of the acronym NHP to define the claimed nucleic acids is not appropriate and does not impart a clear functional or structural definition.

Claims 1-6 are indefinite over the recitation of "nucleotide sequence first disclosed in the NHP gene" and "nucleotide sequences uniquely disclosed in the NHP gene" because it is unclear as to which nucleotide sequences were first disclosed in Applicants NHP sequences and which sequences were already known in the art. Since nucleotide sequences already existed at the time

the invention was made but may not have been characterized it is unclear as to what would be a nucleotide sequence first disclosed in the NHP gene.

Claims 2, 4 and 6 are indefinite over the recitation of "stringent conditions" because the claims do not clarify if the conditions are high stringency, moderate stringency or low stringency. The specification does not provide a clear definition for this phrase and there is no art recognized definition for this phrase. Accordingly, it is unclear as to what would constitute stringent conditions.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg (Accession No. AI300504; reference "BH").

Strausberg discloses a nucleic acid molecule comprising a nucleotide fragment which shares sequence identity with instant SEQ ID NO: 1. Accordingly, Strausberg teaches a nucleic acid comprising a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO:

1. The nucleic acid molecule of Strausberg also contains 24 nucleotides identical to those set forth in SEQ ID NO: 1.

7. Claim 2 is rejected under 35 U.S.C. 102(3) as being anticipated by Hair et al (U.S. Patent No. 6,300,127).

Hair et al discloses a LIM nucleic acid molecule comprising a nucleotide fragment which shares sequence identity with instant SEQ ID NO: 1. Accordingly, Hair et al teaches a nucleic acid comprising a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 1.

8. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Schiaffino (1995, GenBank Accession No. X83543).

Schiaffino discloses a nucleic acid molecule comprising a nucleotide fragment which shares sequence identity with instant SEQ ID NO: 3. Accordingly, Schiaffino teaches a nucleic acid comprising a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 3.

9. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Waterston (June 1998, GenBank Accession No. AC004958; reference "BI").

Waterston discloses a nucleic acid molecule comprising a nucleotide fragment which shares sequence identity with instant SEQ ID NO: 5. Accordingly, Waterston teaches a nucleic acid comprising a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO:

5. The nucleic acid molecule of Waterston also contains 24 nucleotides identical to those set forth in SEQ ID NO: 5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

February 19, 2002

CARLA J. MYERS
PRIMARY EXAMINER